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Weenna Bucay-Couto

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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER

BETTON, TIMOTHY E

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,601	Applicant(s) BUCAY-COUTO ET AL.	
	Examiner TIMOTHY E. BETTON	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-38 is/are pending in the application.
- 4a) Of the above claim(s) 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-21, and 33-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Remarks filed on 17 September 2008 have been acknowledged and duly made of record.

Response to Arguments

Applicants' aver the Rejection under 35 U.S.C. § 102(b) as being anticipated by Devane et al. Applicants' response has been considered and is found persuasive and the rejection is hereby withdrawn.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, there is clear teaching, suggestion, and motivation to combine and/or modify the teachings of Hauschild, Escandon, Unger I, and Unger II because the references in combination reasonably make the limitations of the claimed invention obvious.

In view of this, it is noted that the primary reference Seo et al. has not been averred by applicants. For the reasons already established based upon the teachings of said Seo et al., the references which follow Seo et al. were employed to show motivation as to why the one of skill would incorporate the components of Gentz, Desai, Cortese, Glajch, Hauschild, Escandon and the four Unger references as disclosed.

In response to applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants' arguments are considered but are not found persuasive because the references as applied in the previous rejection adequately suggest and support the invention. But upon further consideration the following new rejection is made.

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 6-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (USPN 6,277,391 B1) and Desai et al (USPGPUB 2003/0130575 A1) in view of Gentz et al. (USPN 6,869,927 B1), Cortese et al. (USPGPUB 2002/0010150 A1), and Glajch et al. (USPN 5,147,631).

Seo et al. teach a composition and method for treating diseases and disorders of the prostate such as prostatitis, benign prostatic hypertrophy, and prostate carcinoma. *The prostate is treated by intraprostatic injection of a biodegradable sustained release formulation. By injecting the treatment substance directly into the prostate, improved treatment results are obtained with a much lower treatment substance dosage.* Additionally, by incorporating the treatment substance into a biodegradable sustained release formulation, the need for frequent repetition of injections is eliminated (abstract only).

Accordingly, Seo et al. teach a step which discloses the exact dimension of particles size as disclosed in instant claim 6 (see column 16, lines 19 and 20). The teachings of Seo et al. are directed to a treatment for prostatic cancers *inter alia*, principally, which reasonably is encompassed by the limitations of the current invention. Instant claim 1 discloses *comprising*

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language which makes the claim broad and not exclusive. Therefore, the teachings and modifications of Desai and Seo et al. reasonably extend in obviousness over the claimed invention.

Seo et al. teach at column 3 at line 26 that in order for the therapeutically effective substance to be viable it *will* be combined with biodegradable polymer.

Seo et al. does not teach the limitations drawn to a specifically named biodisintegrable polymer.

However, Desai et al. teach methods and apparatus for body tissue treatment using laser energy and electromagnetic radiation, and more specifically to methods and apparatus wherein laser energy and electromagnetic radiation are delivered to target tissue for controlled heating of tissue and for enhancing localized tissue *necrosis* thermal energy can be generated from Laser, microwave, electromagnetic radiation, RF and ultrasound or combinations of energy sources [0003] [0005].

Desai et al. teach solid and semi-solid dosage forms [paragraphs, 68, 9th line from bottom; (col. 1, last 2 lines from bottom)].

Specifically, Desai et al. teach a method of Laser treatment specifically for a prostate for achieving prostate ablation for treatment of BPH and prostate cancer, bladder cancer and lower urinary tract [...][0095].

However, Gentz et al. reasonably encompasses the limitations disclosed in claims 9-20 by teaching [...] liquid injectable formulations of keratinocyte growth factor-2 (KGF-2) and derivatives thereof (column 1, lines 19-24, and column 4, line 11-67), comprising KGF-2 polypeptides and sodium chloride as a tonicifier at a concentration of from about 0 to about 150

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mM (NaCl) (column 4, line 34). Sodium chloride of about 150 mM is reasonably construed to serve as a chemical ablation agent in amount effective to cause tissue necrosis and to reasonably serve as a **biodisintegrable viscosity adjusting agent** in an amount effective to render the formulation highly viscous (see instant specification, page 3, paragraph 0019, line 1 to paragraph 0020, line 2; and page 5, paragraph 0026). Gentz et al. teach that the KGF-2 to be used for therapeutic administration may be sterile and that sterility is readily accomplished by filtration through sterile filtration membranes (column 14, lines 33-35). Sodium chloride is reasonably construed to be an osmotic-stress- generating agent in view of applicant's disclosure that "[I]n some embodiments, the ablation agents are osmotic-stress-generating agents, for example, a salt, such as sodium chloride (page 3, paragraph 0020, lines 1-2)." Gentz et al. teach that the formulations may employ "suitable pharmaceutical diluents," including but not limited to, saline, buffered saline, dextrose, water, glycerol, ethanol, and combinations thereof (column 12, lines 29-34). "Suitable pharmaceutical diluents and combination thereof" is reasonably construed to encompass an amount of water and ethanol suitable for the preparation of a sterile injectable formulation as claimed in the instant application (specification page 5, lines 1-2)..

Gentz et al. teach that thickening agents are used to increase the viscosity of the formulation e.g. carboxymethyl cellulose (CMC), hydroxyethyl cellulose (HEC), hydroxypropylmethyl cellulose (HPMC), natrosol, and carbomers (column 2, lines 3-7). Gentz et al. teach examples of etherified cellulose to include alkyl celluloses e.g. methylcellulose, hydroxyethyl cellulose, hydroxyl propyl cellulose, hydroxyl propyl methylcellulose, and the like (column 9, lines 5-9).

Gentz et al. teach that when thickening agents are added to the injectable formulations, salts and buffering agents may be added or removed from the formulation for optimal stability (column 9,

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second paragraph, lines 1-3). Gentz et al. teach that gelling agents may be added to the injectable formulations, including vinyl polymers, polyoxyethylenepolyoxypropylene copolymers, polysaccharides, proteins, poly(ethylene oxide), acrylamide polymers and derivatives and salts thereof; useful polysaccharides include cellulose derivatives, glycosaminoglycans, agar, pectin, alginic acid, dextran, starch, and chitosan (column 10, lines 19-51). Based on this teaching, ionically cross-linkable polymers such as alginate polymer are reasonably within the capabilities of someone of skill in the art.

Thus, based on the teaching of Gentz et al., someone of skill in the art would have been motivated to create the instant claimed inventive concept. Thus, someone of skill in the art at the time the instant claimed invention was made to create the instant invention with a reasonable predictability in view of the general knowledge of the state of the art.

Gentz et al. does not teach solid and semi-solid formulations. However, the one of skill would readily incorporate the teachings of Cortese to reasonably provide further motivation to combine based upon characterization optimization of the teachings of Gentz et al. in view of Cortese et al.

Cortese et al. teach cross-linkage of polymers (paragraph 69).

Accordingly, on page 7 under Uses of PA/PO Compositions, Cortese et al. teach embodiments drawn specifically to the administration via injection with a needle (104, last line).

Cortese et al. essentially teach in paragraph 105 embodiments which are reasonably obvious over the claims in the instant invention drawn to solid and semi-solid dosage forms.

Cortese et al. teach prostate surgery (page 14, claim 39, line 5). Thus, the polyacids of Cortese et al. make the biodegradable binder obvious to be included in the formulation in view of the claimed invention and all elements represented by Cortese et al.

Cortese et al. does not teach an imaging contrast medium or the micron dimensions according to claim 6.

However, Glajch et al. is added to show the general knowledge in the art regarding formulations comprising contrast agents, polymers, and solid particles. Glajch et al. teach ultrasound contrast agents comprising porous particles of an inorganic material having an average particle diameter of about 0.05 to 500 microns and containing entrapped gas or liquid; the inorganic material includes monomeric and polymeric forms of one or more of the following: borates, aluminas, carbonates, silicates, silicas, aluminosilicates, phosphates, and organic or inorganic cationic salts thereof (column 2, lines 11-27). This teaching is reasonably construed to satisfy the "wherein the plurality of solid particles is selected from calcium carbonate particles ..." instant claim limitation. For parenteral use, the particles are preferably about 0.2-10 microns in average diameter (column 2, lines 33-34). Glajch et al. teach that these contrast agents are useful for ultrasound imaging of a body organ system (column 2, lines 66-68).

Based on the teaching of Glajch et al. of ultrasound contrast agents useful for ultrasound imaging of a body organ system, someone of skill in the art would have been motivated to combine the teachings of the above cited references to arrive at the instant claimed invention. Thus, someone of skill in the art would have deemed it obvious at the time of the invention was made to create the instant invention with reasonable obviousness.

Desai et al. teach methods and apparatus for body tissue treatment using laser energy and electromagnetic radiation, and more specifically to methods and apparatus wherein laser energy and electromagnetic radiation are delivered to target tissue for controlled heating of tissue and for enhancing localized tissue *necrosis* thermal energy can be generated from Laser, microwave, electromagnetic radiation, RF and ultrasound or combinations of energy sources [0003] [0005].

Desai et al. teach solid and semi-solid dosage forms [paragraphs, 68, 9th line from bottom; 91, last 2 lines from bottom].

Specifically, Desai et al. teach a method of Laser treatment specifically for a prostate for achieving prostate ablation for treatment of BPH and prostate cancer, bladder cancer and lower urinary tract [...][0095].

Desai et al. does not teach a weight average particle size between 1 and 100 microns in largest dimension.

Thus, it would have been prima facie obvious to the one of skill at the time of invention to see a reasonable expectation of success via the combining together the teachings of Seo, Gentz, Desai, Cortese and Glajch.

Desai et al. teach embodiments drawn to the necrosis of tissue which suggests and supports obviousness over the claimed invention with the exception of teaching 1 to 100 microns. Seo et al. overlaps the teachings of Desai while teaching the range limitation of claim 6. Gentz et al. reasonably encompasses the teachings drawn to biodegradable binders by disclosing all the essential elements contained within claims 7 and 9-20. The one of skill is inclined to recognize the limitation drawn to *encapsulated* as reasonably encompassed by the broadest meaning attributed to the microparticles of Desai et al. reference. Cortese et al.

exemplify the teachings of Gentz et al. by expressly teaching a solid/semi-solid formulation. Glajch provides further motivation via the teaching drawn to an imaging contrast agent.

Claims 2-4 and 33-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (USPN 6,277,391 B1), and Gentz et al. (USPN 6,869,927 B1) in view of Desai et al (USPGPUB 2003/0130575 A1), Cortese et al. and Glajch et al. (USPN 5,147,631) as applied to claims 1 and 6-21 above, and further in view of Hauschild et al. (USPN 6,905,475), Escandon et al. (USPN 7,015,253) and Unger et al. (USPN 5,733,572; USPN 5,733,572; USPN 6,443,898; USPN 6,123,923).

Hauschild et al. teach a method and surgical instrument for treating prostate tissue including a surgical instrument having a main body, a needle deployment port, a needle, first and second handles and a lockout release mechanism to limit needle extension. Additionally, a kit includes the surgical instrument, together with a cystoscope, and optionally a syringe and reservoir of ethanol. The method includes needle-less injection and visualizing the ethanol injection by delivering both an echogenic agent and ethanol either by needle or needle-less injection or by providing an ultrasonically visible marker near the tip of the ethanol delivery cannula. The method also includes extending the needle transversely of the instrument housing using a link assembly (Abstract).”

In patented claim 1, Hauschild et al., teach a method of injecting a drug into prostate tissue. Column 3, line 30 specifically teaches the use of a surgical instrument: the scope allows visual positioning of the needle port against the urethra adjacent to the lobe of the prostate to be treated. The needle is advanced one detent click at a time to place the needle tip in the adenoma. A small volume of an active ingredient such as anhydrous alcohol is slowly injected into the

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tissue. The urethral lumen may be continuously irrigated while the ethanol is being administered.

The embodiment suggests a process similar to a manner of necrotizing compromised tissue.

However, in other aspects of the invention in Figures 9 and 10, column 6, lines 35-40, there is a disclosure of transurethral ablation. Furthermore, in column 1, line 39-57, ablation is initially disclosed but in relation to laser treatments. Additionally, it is disclosed that ablation is associated with the process of surgically damaging prostate tissue. One of ordinary skill in the art would readily recognize that as a result of surgically damaging prostate tissue, there is certain to be necrotizing of said tissue. However, removal or excision of such compromised tissue is not as apparent. The dosage form of the active ingredient as disclosed in a specific embodiment is a sterile semi-solid in consistency, i.e., GELFOAM® Sterile Powder.

In column 10 of Hauschild et al., patented claim 1 is obvious over subject claim 8, which discloses an injection or insertion into the tissue via a jet injector. The referenced patent teaches a surgical instrument disclosed in column 5, lines 49 to 55 similar to the jet injector apparatus disclosed in instant claim 8. In addition, said instrument contains a disclosure as to make the needle more visible on ultrasound and ways to make the fluid delivered more visible which is similar to the disclosure of a contrast agent in instant claim 21.

Escanden et al. teach, "The present invention provides treatment regimens for treating diseased prostate tissue, including the steps of chemically ablating prostate tissue and coadministering an antiandrogen. In some embodiments, injection of ethanol, or an injectable gel comprising ethanol, into prostate tissue, chemically ablates prostate tissue. Steroidal and non-steroidal antiandrogens are suitable antiandrogens. One suitable non-steroidal antiandrogen is bicalutamide. The treatment regimen is suitable for treatment of prostate tissue diseases

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including benign prostatic hyperplasia and prostatic carcinoma. The invention further provides a treatment regimen for treating benign prostatic hyperplasia, including the steps of damaging prostate tissue and coadministering an antiandrogen. Also provided by the present invention is a kit for treating a human male, including a means for necrosing prostate tissue, an antiandrogen drug, and a means for administering the antiandrogen drug. A kit including a first surgical device for delivering a chemoablation fluid to prostate tissue transurethrally, an antiandrogen drug such as bicalutamide, and a second surgical device for administering the antiandrogen drug, is further provided (Abstract)."

Specifically, Escanden et al. is obvious over instant claims 20 and 21 in instant application. In column 5 and 6 of referenced patent, several embodiments of chemoablation are cited. In one embodiment, the present invention provides a treatment regimen for treating diseased prostate tissue. The treatment regimen includes the steps of chemically ablating prostate tissue sufficiently to elicit a reparative process in the absence of further treatment; and coadministering a therapeutically effective amount of an antiandrogen.

"As used throughout this specification, the terms "ablate," "ablation" or "ablating" of tissue means causing a reduction in tissue mass. One suitable manner of ablating tissue is by causing a decrease in the number of tissue cells. The phrase "chemical ablation" includes processes whereby tissue mass is reduced by action of a chemical or biological agent on the tissue. The size of the prostate is reduced relative to its size prior to treatment by the treatment regimen. The treatment regimen is suitable for treatment of prostate tissue diseases including BPH and prostatic carcinoma. One suitable procedure for chemically ablating prostate tissue in accordance with the treatment regimen is by injection of ethanol (absolute

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alcohol) into the prostate to be treated. Ethanol preferably is injected deeply into prostate tissue through a needle that is positioned transurethrally, such as in the procedure known as transurethral ethanol ablation of the prostate (TEAP). The ablating action of ethanol is due to several processes, including dehydration of cells, coagulation of proteins, and thrombosis of vessels that feed the tissue.”

Column 17, the surgical instrument called a PROSTAJECT is similar in scope to the jet injector as disclosed in instant claim 8. Further, on line 11 the means for necrosing prostate tissue is disclosed. In particular, the ethanol is intended to be used as an ablating or necrosing agent, and the antiandrogen is intended to be coadministered according to any of the treatment regimens described above. The antiandrogens described above are suitable for the combination medicament. Bicalutamide in particular is a suitable non-steroidal antiandrogen (column 18). In column 10, line 11 an additive for enhancing the visibility of the chemoablation fluid may be incorporated via specialized dyes. This similarity is found likewise in instant claim 21, which discloses imaging via contrast agents.

Hauschild et al. do not directly teach specific claims in regard to necrotizing prostate tissue, however a combination of a contrast agent (i.e., visible marker) and an ultrasonic beacon are disclosed within patented claims in order to facilitate detecting and determining amount of agent to specific site of prostate tissue via surgical instrument. Further, referenced patent does not teach an identical model of a jet injector as disclosed in instant claim 8, however the apparatus used is significantly similar in design, operation, and effect.

Escanden et al. does not teach the identical embodiment of contrasting agents as disclosed in instant application. Further Escanden et al does not teach treatment to other body regions except to prostate tissue.

However, the Examiner refers to Unger et al., which discloses a filtration process by which the resultant active ingredient (unfiltered volume) yield a volume of 80-90% of the unfiltered volume. This disclosure reasonably makes the limitations of claims 33-36 obvious based upon the variable range and the comprising language employed.

Unger et al. (6443898) teach microspheres (bead, instant claim 3) that are disclosed to have a semi-solid consistency and are intended for use in a therapeutic drug delivery system [Detailed Description Text (87)].

Unger et al. (6123923) teach the incorporation of a glycolic acid polymer (film-forming material at the surface) so as to maintain stability of dosage form in association with solid matrices [Detailed Description Text (94)]. Further, Unger et al. teach fiber (instant claim 4) as a dosage form directed toward use as a contrast agent (instant claim 21) that is used in conjunction with ultrasound for surgical procedures [Drawing Description Text (10)].

Furthermore, instant claim 2 discloses a dosage form in the shape of a cylinder. The inner space of a needle (injection dosage form) cannula is shaped cylindrically, so as to accommodate various formulations that may be semi-solid within the needle housing, thereby properly addressing said limitation.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods and devices of Hauschild et al. and Escanden et al. to include administration of a chemical ablation agent/biodisintegrable formulation for

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insertion or injection in view of the motivation of Unger et al. as disclosed above. There is substantial documentation in the prior art, which suggests the motivation via obviousness to combine the teachings of Hauschild et al. and Escanden et al. by reasonable explanation of producing an effective chemoablative/ therapeutic drug delivery system. It would instantly be obvious to one of ordinary skill in the art to see the motivation of Unger et al. in regard to disclosures/data supporting detailed explanations to purport the optimal scope of the subject invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617